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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,363	05/25/2001	Dirk M. Anderson	2852-E	4679

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EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/865,363

Applicant(s)

ANDERSON ET AL.

Examiner

Eileen O'Hara

Art Unit

1646

~ The MAILING DATE of this communication appears on the cover sheet with the correspondence address ~

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-38 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36,37 and 42-49 is/are rejected.
- 7) ☒ Claim(s) 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Claims are pending in the instant application. Claims 36 and 38 have been amended, claims 39, 40 and 41 have been canceled and claims 42-49 have been added as requested by Applicant in Paper Number 10, filed January 30, 2003.

***Priority***

2. Applicants' amendment to the specification to update the status of 09/577,780 is acknowledged.

***Drawings***

3. The corrected or substitute drawings were received on January 30, 2003. These drawings are acceptable.

***Oath/Declaration***

4. The substitute declaration submitted by Applicants is acceptable.

***Withdrawn Objections and Rejections***

5. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

***Specification***

6. The disclosure is objected to because of the following informalities: there is insufficient antecedent basis for a composition comprising an antibody to RANKL of SEQ ID NO: 13.

Although the specification at page 27, lines 31-34 teach antibodies as components of diagnostic or research assays for RANKL, there are no compositions taught.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 36 and 42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 36 and 42, as written, do not sufficiently distinguish over antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 36, 37 and 42-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36, 37 and 42-49 are indefinite because claim 36 encompasses an antibody that binds to a RANKL polypeptide, and claim 42 encompasses an antibody that “specifically binds”. The specification does not define the term “specifically binds” and it is not clear what this means, and it is not clear what the difference in scope between “binds” and “specifically binds” is.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. Claims 36, 37 and 42-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al., U.S. Patent No. 6,242,586, effective priority date December 13, 1996 (provisional 60/032,846), cited by Applicants in IDS Paper No. 5.

Claims 36, 37 and 42-49 encompass antibodies to the RANKL polypeptide of SEQ ID NO: 13 or the recited fragments of the polypeptide, which may be monoclonal, and compositions comprising antibody. The effective filing date for the protein of SEQ ID NO: 13 is March 7, 1997, since it was first disclosed in provisional 60/077,181, filed on that date.

Gorman et al. disclose a murine polypeptide identified as 499<sup>E9</sup> that is 84% identical to the human polypeptide of SEQ ID NO: 13 of the instant application (see attached sequence alignment). Since the proteins are orthologs and are highly similar, antibodies to the protein of Gorman et al. would also bind to the protein of SEQ ID NO: 13 and the recited fragments of SEQ ID NO: 13 of the instant application. Gorman et al. teach antibodies to the protein of SEQ ID NO: 2, which may be monoclonal, and also teach compositions comprising antibody (column 2, line 66 to column 3, line 24, column 10, lines 25-27, column 15, line 4 to column 16, line 42, Example 5). Therefore, Gorman et al. anticipates the claims.

### ***Conclusion***

10.1 Claim 38 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10.2 Claims 36, 37 and 42-49 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER